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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/184,043	11/02/1998	HANS HORNAUER	P564-8023	3802
6449	7590	10/23/2006	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			CEPERLEY, MARY	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/184,043	HORNAUER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Mary (Molly) E. Ceperley	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 12 July 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 14 and 61-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 14, 63 and 74 is/are allowed.
- 6) Claim(s) 61, 62, 64-73 and 75-77 is/are rejected.
- 7) Claim(s) 66 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>09/26/2006</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|   | 6) <input type="checkbox"/> Other: _____                          |

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**1)** Applicant should correct the numerous misspellings of the terms "solid" (e.g. claims 65, 66, 71, 74) as well as the term "binding" (e.g. claims 64-66).

**2)** The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**3)** Although specific claims may be discussed in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

**4)** Claims 61, 62, 64-73 and 75-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**a)** For claim 61, there is no antecedent basis in claim 14 for the term "an analyte-specific modified solid phase reactant". If applicant intends this term to refer to the product described in claim 14, step (a), claim 61 should refer to the product prepared in step (a) of claim 14. As written, for claim 61 it is unclear what is meant by the terms "modified" and "reactant". Additionally, the Markush group which defines "an analyte-specific modified solid phase reactant" recites members which appear to refer to moieties which would be reactive with the corresponding analytes but which are not related to the "solid phase".

**b)** For claims 64 and 65, it is unclear what moiety the "solid phase" is "immobilized" to. Is this "immobilization" intended to refer to the interaction of the "solid phase" with the "preformed conjugate" or does the "immobilization" involve the attachment of the "solid phase" to a different, unspecified moiety?

**c)** For claim 66, there is no antecedent basis in claim 14 for the term "modified solid phase reactant". The terms used in claim 14 should also be used in claim 66.

**d)** For claim 68, there is no antecedent basis in claim 14 for the term "modified analyte specific solid phase reactant" in claim 14. It is unclear what noun is being modified by the term "which is incubated". It is unclear what constitutes a "further (?) alkylene oxide modified binding molecule (?) which ("binding molecule?") acts as a blocker".

**e)** For claim 69, it is unclear what is meant to be encompassed by the term "non-analyte specific molecules" (molecules that don't react with the analyte? or molecules which are "non-analyte" [i.e. not analytes but are "specific" for what moiety?]).

**f)** For claim 73, there is no antecedent basis in claim 14 for the term "an alkylene oxide modified analyte specific reactant". The terms used in claim 14 should also be used in claim 73. It is unclear what is meant by the term "an alkylene oxide modified blocker". It is unclear in which step and how the "combination" is used in the method defined in claim 14.

**g)** Since claim 14 recites no "region" or "spatially limited test area", for claims 75 and 76 it is unclear on what moiety the "region" and "test area" are present.

**h)** For claim 77, there is no antecedent basis in claim 14 for the term "different(?) analyte-specific solid phase reactants". The terms used in claim 14 should be used in claim 77. It is unclear what is meant by the term "different".

**i)** Claim 62 is indefinite for the reason that there is no positive method step recited which would cause the effect of reducing "unspecific binding to the solid phase". It is unclear what additional step(s), if any, is required to bring about the desired effect or whether the effect is inherent in the method of claim 14 (in which case claim 62 is a duplicate of claim 14).

**j)** For claims 75 and 76, it is unclear where the "test area" is located. There is no antecedent basis in claim 14 for the term "an analyte specific region".

**5)** Claim 66 is objected to as being a duplicate of claim 14 since both claims are limited to the same method steps involving the same reactants.

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**6)** Claims 14, 63 and 74 are allowed.

**7)** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 11, 2006

*Mary E. Ceperley*  
Mary (Molly) E. Ceperley  
Primary Examiner  
Art Unit 1641